EXHIBIT CC

Clinical Expert Report
GYNECARE PROLIFT+M* Pelvic Floor Repair System

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MANUFACTURER'S STATEMENT ON THE CLINICAL DATA USED TO AFFIX CE-MARK:

The following clinical evaluation is based on the assessment of the risks and the benefits, associated with use of the device through:

- A compilation of relevant scientific literature that is currently available, as well as a written report containing a critical evaluation of this compilation.

DEVICE DESCRIPTION & BACKGROUND:

The GYNECARE PROLIFT+M System is a modification to the currently marketed GYNECARE PROLIFT System. Both systems consist of pre-cut mesh implants and a set of instruments to facilitate mesh implant placement. The systems differ in the mesh implant that is used along with minor changes in the packaging of the mesh to accommodate additional requirements for a mesh implant that includes an absorbable component. These changes include an increase in the length of the posterior strap and changes in the posterior arms.

The indication for use for the GYNECARE PROLIFT+M System is unchanged from that of the currently marketed GYNECARE PROLIFT System. The system is indicated for tissue reinforcement and long lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

The instruments, which are unchanged include:

GYNECARE PROLIFT Guide

The GYNECARE PROLIFT Guide is a single-patient-use instrument designed to create tissue paths to allow placement of the Total, Anterior, and Posterior mesh implants and to facilitate placement of the GYNECARE PROLIFT Cannula. Its length and curvature are specifically designed to create proper placement paths for all mesh implant straps. The GYNECARE PROLIFT Guide is suitable for use on both sides of the patient.

GYNECARE PROLIFT Cannula

The GYNECARE PROLIFT Cannula is a single-patient-use instrument used in conjunction with the GYNECARE PROLIFT Guide to facilitate passage of the implant straps while protecting the surrounding tissue. Each GYNECARE PROLIFT Cannula is placed over the GYNECARE PROLIFT Guide before passage and remains in place after the GYNECARE PROLIFT Guide is withdrawn.

GYNECARE PROLIFT Retrieval Device

The GYNECARE PROLIFT Retrieval Device is a single-patient-use instrument designed to facilitate placement of the mesh implant straps. The GYNECARE PROLIFT Retrieval Device is passed through the previously positioned GYNECARE PROLIFT Cannula until its distal end is retrieved through the vaginal dissection. The distal end of the GYNECARE PROLIFT Retrieval Device has a loop to securely capture the mesh implant strap as the strap is drawn out through the GYNECARE PROLIFT Cannula.

The mesh, mesh packaging and the posterior mesh strap location are changed as described below:

GYNECARE GYNEMESH M

GYNECARE GYNEMESH M is manufactured from approximately equal parts of absorbable poliglecaprone-25 monofilament fiber and non-absorbable polypropylene monofilament fiber. The polymer of the undyed and dyed polypropylene fiber (phthalocyanineblue, Color Index No.: 74160) is identical to the material used for dyed / undyed PROLENE* Polypropylene Suture material and the mesh that is used in the original GYNECARE PRLOFT System. Blue PROLENE Suture monofilaments have been incorporated to produce contrast striping in the mesh.

Poliglecaprone-25 fiber consists of a copolymer containing glycolide and ε-caprolactone; this copolymer is identical to the material used for MONOCRYL* (Poliglecaprone 25) Suture. The absorbable poliglecaprone part of the mesh aids handling, making intraoperative manipulation and positioning of the mesh easier. After absorption of the polyiglecaprone-25 component, only the polypropylene mesh remains.

Summary of Requirements

The evidence required in order to demonstrate that the use of device meets the claims involves:

a) Confirming that the market acceptance of the GYNECARE PROLIFT System includes acceptance that the product meets the claims for use

b) The modifications made to the mesh for the GYNECARE PROLIFT+M System are shown to be acceptable, that the modified system will continue to meet claims.

These two requirements are addressed in order, first a review of the literature on the GYNECARE PROLIFT System followed by a discussion of the modification of the system to produce the GYNECARE PROLIFT+M System.

LITERATURE REVIEW:

Method

A literature search was conducted in March 2007 using the following search terms: "Pelvic Organ Prolapse", "Anterior Colporrhaphy", "Posterior Colporrhaphy", and "Prolapse Repair Mesh". These terms were chosen to include articles that describe vaginal surgery for the treatment of pelvic organ prolapse. The search was performed using Pub Med provided as an online service by National Center for Biotechnology Information (NCBI) that includes the National Library of Medicine (NLM) with responsibility for MEDLINE. Limits and manual corrections were applied to the search results as described in the table below:

Search Term	Pelvic Organ Prolapse	Anterior Colporrhaphy	Posterior Colporrhaphy	Prolapse Repair Mesh
Records returned	634	195	96	165
Published in last 3 years, English Only	320	34	28	73
Clinical Trial	**26**	**4**	**3**	**5**

Meta-Analysis	**0**	**0**	**0**	**0**
Controlled Clinical Trial	**0**	**0**	**0**	**0**
Review	**55**	**7**	**5**	**13**

The topics chosen represent a straightforward list of search terms that would yield an adequate literature sample. Many overlapping articles were found in the lists, demonstrating good coverage of the field. The list of articles, with applied limits, were printed and reviewed for appropriateness. Articles were excluded if the title indicated the topic was not relevant to a review of surgical intervention for pelvic organ prolapse or if they were found on more than one list. Examples of excluded topics include urodynamics, incontinence, sexual function, and development of assessment scales, epidemiology, pharmaceutical studies, and radiology. The final list included eight papers describing clinical trials and sixteen review papers. Eleven review papers and six clinical trial publications were readily available for review and inclusion in this summary. Although not an extensive list of papers on this topic, the inclusion of nine review papers greatly expands the literature represented. Additional literature, collected during the development of prior products in the field of pelvic organ prolapse repair was also consulted.

The selected articles are appropriate to represent current interventions used to address the conditions the GYNECARE PROLIFT Pelvic Floor Repair System is intended to manage. The articles describe both the anterior, posterior (and combined repairs) with the inclusion of additional implant material to provide support for the prolapse repair.

Introduction

Fascial defects are thought to be associated with some deficiency in the patient's connective tissue.[7] These defects can lead to abdominal, inguinal hernias or pelvic organ prolapse. Pelvic prolapse is also associated with pregnancy and childbirth injury, at least in the non-elderly patient.

Pelvic organ prolapse is thought to result from a stretching, weakening, or tearing of the soft tissue structures that support the pelvic organs. It is believed these tissues are compromised because of a weakened or damaged *levator ani* muscle group. This muscle group is the platform at the base of the pelvis responsible for supporting the pelvic organs. As the damaged *levator ani* drops, the opening (hiatus) between the *levator ani* is widened. Intra-abdominal forces are then relatively unopposed by the weakened muscle leading to increased forces applied to the connective tissue support structures, which results in their tearing or stretching.

Surgical options are many, made more challenging as multiple weakened regions often occur in a patient and incomplete correction of any may lead to worsening of other regions as loads are transferred.

Reinforcement with Synthetic Materials

The surgical procedures to treat pelvic organ prolapse involve tightening and reinforcing of weakened tissue, suspension of unsupported structures, or a combination of both. When concerns exist about the quality of the patient's native tissue, surgeons may choose to utilize several materials including: autologous tissue, cadaveric material, allograft material, synthetic absorbable mesh, and synthetic permanent mesh. Birch, in a 2005 review paper[1] acknowledged the need for some means of reducing the unacceptably high reoperation rate for persistent or recurrent pelvic prolapse, with

recurrence rate often quoted at 30% or higher. He referred to recently developed prosthetic systems that have been developed for minimally invasive treatment of urinary incontinence.

Synthetic materials in the form of mesh have long been considered for reinforcement of weakened pelvic floor tissue. Synthetic meshes, first used for abdominal wall hernia repairs, are able to provide additional tissue support in cases where native tissues are inadequate. Synthetic meshes have been used with increasing frequency in gynecologic surgery over the past 30 years[2] and they have been placed using an abdominal or a vaginal approach. However, they do add the risks of exposure, rejection and changes to tissue properties.[3]

Problems with exposures of permanent mesh placed in the body are not unique to pelvic prolapse surgery.[4,5] As observed in hernia repair, several factors are thought to contribute to mesh exposures. These include the quality of dissection and suture closure, host factors like nutritional status and blood flow, the presence of infection, foreign body reactions, and finally, mesh characteristics such as material, filament size, mesh porosity, rigidity, and mesh density.

When he reviewed a series of 63 women treated at two referral urogynecological centers in Italy, Milani[6] concluded that good anatomical results where achieved when anterior and posterior vaginal prolapse was repaired with PROLENE mesh, but reported a high rate of morbidity. Because of this experience, he concluded that PROLENE Mesh should not be used to reinforce these repairs. His two main concerns were erosion of the material through the vaginal wall and *de novo* dyspareunia. Mesh erosion through the vaginal wall was observed in 6.5% of the cases occurring after a mean time of 14 months. The author felt the reported change in sexual function among women treated in this series was the most clinically relevant finding. He noted an earlier study, involving a series of patients who underwent similar posterior repair without the use of mesh reinforcement also reported of a high rate of *de novo* dyspareunia after surgery, so the association with mesh is not clear.

In their review of fascial defects and the use of implants in pelvic organ prolapse repair, Deprest et al[7] restated the classification of synthetic materials attributed to Amid, with most authors considering Type I: Totally macroporous monofilament polypropylene as the most logical choice for pelvic floor repair. Heubner and colleagues[8] described the ideal material as flexible and durable, a monofilament structure with a macropore size; a material that remains flexible (or dissolves) after appropriate collagen deposition for use as a synthetic graft. Although the original polypropylene meshes such as MARLEX Mesh and PROLENE Mesh meet these characteristics, surgeons have begun using polypropylene meshes that have a lower density and larger pore size than these earlier macroporous monofilament polypropylene meshes. The density is reduced by 50% (from 95 g/m^2 for MARLEX Mesh to 45 g/m^2 for GYNEMESH PS Mesh, the pore size increased from 0.6mm to 2.4mm).[9] These lower density, or so-called lightweight, meshes have been predicted, in hernia models, to induce less foreign-body response and better tissue incorporation.[10] The changes in tissue response to these materials are thought to have a positive impact on both the rate of material exposure and tissue stiffening related complications.

Reported experience with GYNECARE PROLIFT Pelvic Floor Repair System

Fatton and colleagues[11] reported their experience with the use of the PROLIFT System to repair pelvic organ prolapse. The study included 110 consecutive subjects at three French centers who were evaluated retrospectively. The study included women with recurrent prolapse and significant primary prolapse, all were at least Stage III (ICS Staging) before surgery. A total repair was performed in slightly more than ½ of the subjects; the remaining cases were roughly split between anterior and posterior procedures with a slightly higher number of isolated posterior procedures.

Intraoperative problems were few; three required intervention, a bladder perforation requiring suturing and two subjects with hematoma that required subsequent surgical drainage prior within the first eight days post procedure. At early follow-up (minimum 3 months) an anatomic failure rate of 4.7% was observed, and there were five subjects with mesh exposure, two requiring a minor surgical intervention. The authors concluded that the procedure and implants were safe, with early indication of effectiveness.

Two additional papers[12,13] described management of perioperative and posteroperative management of problems associated with the PROLIFT System. Collinet reported a manageable rate of mesh exposure problems among a series of 227 patients who underwent the system procedure for the treatment of pelvic prolapse, and identified technical factors that appeared to influence the probability of mesh exposure occurring. These factors included concurrent vaginal hysterectomy and the use of an extensive "T" shaped vaginal incision.

Altman[14] and colleagues reported on a Scandinavian multi-center series of 248 women who had undergone repair with the PROLIFT System with a focus on perioperative morbidity. In this series, most patients had undergone at least one prior pelvic floor repair procedure and 56% of the procedures were for recurrent prolapse. Complications considered serious by the authors were reported in 4.4% of the subjects, almost all were visceral injuries, which included bladder, rectal and urethral perforation. One patient experienced significant (>1000 ml) blood loss. Additionally, close to 15% of the patients experienced complications the authors defined as minor. The authors acknowledged that the large number of repeat procedures likely had an impact on complication rate, operating in the presence of scar tissue and fibrosis adds to the risk. The authors concluded that serious perioperative complications were uncommon after these procedures but care must be taken to detect possible visceral injury at the time of the procedure.

Literature Review Conclusion Statement

The GYNECARE PROLIFT Pelvic Floor Repair System has reported results and surgeon acceptance consistent with a product that meets the claims for use.

Clinical Investigations

No clinical investigations have been conducted on the use of GYENCARE PROLIFT Pelvic Floor Repair System.

Modification of Mesh Implant to produce the GYNECARE PROLIFT+M System:

As described in the earlier PROLIFT System literature review section, synthetic materials have been used to reinforce the deficiencies in native tissue in the treatment of inguinal and incisional hernia defects and pelvic organ prolapse. Reinforcement materials were first widely used in hernia repair and the understanding of their use there has been applied to pelvic organ prolapse repair. In a review paper, Huebner and colleagues[8] in 2006 described the challenges associated with the increased use of surgical mesh in pelvic floor surgery. The selection of a synthetic mesh for pelvic floor repair includes consideration of many characteristics including composition and architecture; these factors influence properties including strength, flexibility, and pore size. Among currently used synthetic meshes, most are in the Amid Classification of Type I, macroporous mesh with a pore size > 75µm. These mesh implants are typically constructed from monofilament polypropylene fibers.

Knitted, polypropylene mesh as a reinforcement for Hernia Repair has been used for 40+ years and is an accepted method for reducing recurrence of abdominal wall defects seen in both incisional and inguinal hernias. However, implantation of polypropylene mesh is associated with an increase in problems associated with the foreign material implant. Complications associated with these materials have led to changes in implant materials and construction with a goal to 1) reduce implant mass and 2) increase the mesh pore size[31]. The impact of such reductions in material mass on the durability of the repair must be considered. Assessing the breaking strength of healthy tissue, *in vivo* measurements of maximum pressure during the stresses of coughing, jumping and Valsalva maneuver, and mathematical modeling of abdominal wall forces, have led to the conclusion that synthetic mesh implants, even the lower mass mesh implants, are significantly stronger than required. [7,10,15 16] For further evidence, Cobb[17] studied the burst strength of three mesh types (MARLEX Mesh, PROLENE Soft Mesh, and ULTRAPRO Mesh) in a porcine hernia model. Testing burst strength five months after implantation demonstrated that even the lowest mass mesh (ULTRAPRO Mesh) exceeded by 2X the estimated burst strength of native abdominal wall fascia burst strength. While providing what he felt was sufficient strength, he noted increased abdominal wall compliance with the lightweight mesh (ULTRAPRO Mesh) when compared to heavyweight mesh. He attributes this improvement to the reduced mass and the larger pore size of the lightweight mesh.

The table below describes material properties and identifies published reports of clinical use of several synthetic mesh implants of different construction and material density.

Table 1 - Characteristics of Various mesh implants

				Literature reports use in		
MESH	Unit Weight (mg/cm2) permanent component	Burst Strength, psi	Maximum Pore Size, mm	Incisional Hernia Repair	Inguinal Hernia Repair	Pelvic Organ Prolapse Repair
PROLENE* Polypropylene Mesh	7.6	234	<1	X[18]	X[19]	X[20]
GYNECARE GYNEMESH* PS Nonabsorbable (PROLENE* Soft Mesh)	4.5	116	2.5			X[21]
MERSILENE* Polyester Fiber Mesh	3.3	83	<1	X[22]		X[23]
VYPRO Mesh	2.5	71 (pre-absorption 90)	4.5	X[24]		X[25]
VYPROII Mesh	3.5		3-4		X[26]	X[27, 28]
ULTRAPRO* Partially Absorbable Mesh (GYNECARE GYNEMESH M* Mesh)	2.8	90 (pre-absorption 135)	5.0		X[29]	

None of the referenced papers indicate failures that could be due to using a mesh implant with inadequate strength, a finding predicted by Cobb who concluded that even the lightest weight meshes currently available exceed the physiologic requirements. In the one literature report of

central mesh failure (the mesh was a heavyweight type mesh, similar to PROLENE Mesh) following hernia repair[30], the authors theorized that the stiffness of the mesh led to an imbalance of elasticity in the abdominal wall with reinforced and non-reinforced regions and this led to failure of the mesh in the markedly overweight patient. The authors felt that a lighter weight mesh, though less strong, might have been less likely to fail.

Reduction of the mass and the increase in the pore size of the mesh implant foreign body are seen to alter the inflammatory response which in turn is likely to alter tissue ingrowth and the resulting properties of the reinforced tissue. As the mass of a mesh implant is reduced and the pore size in increased, the surface area exposed to the host is reduced, and the foreign body reaction to the implant is reduced.[31] [32]

An example of this move towards lowering the mass of implanted mesh is seen in the work of a team of French surgical gynecologists (group TVM) that developed the procedure and mesh implant shape that became the GYNECARE PROLIFT System. During the initial development of the system the group used PROLENE Mesh as the implant in over 100 procedures[33]. When GYNECARE GYNEMESH PS became available, the team readily switched to that implant material in an attempt to address two concerns they observed in the earliest cases; erosion of the mesh through the vaginal wall and tissue contraction leading to stiffening and distortion of the vaginal wall. When the system was commercially released as the GYNECARE PROLIFT System, the implant was GYNECARE GYNEMESH PS Mesh. As shown in Table 1, by using GYENCARE GYNEMESH PS instead of PROLENE Mesh for the same size implant, 1) the implant mass was reduced by almost 50%, 2) the pore size of the implanted mesh was also significantly increased with this change, and 3) the strength of the mesh was reduced. Although direct comparison of subjects treated with the different mesh implants is not possible, as many other changes in the technique were occurring in parallel to the mesh implant change, in practice, the group did prefer the lower mass of the GYNECARE GYNEMESH PS and observed no change in repair effectiveness.

Although further reduction in the mass of the implanted mesh below that of GYNECARE GYNEMESH PS Mesh can be justified based on strength requirements, the handling of such a lightweight mesh during insertion can be challenging. A minimum stiffness along with the ability to maintain shape is necessary to ease placement of the implant. By adding absorbable filaments to a lightweight polypropylene mesh construct, an implant can be produced that provides acceptable handling characteristics during implantation while meeting the goal of reducing the ultimate implant mass.

Design Changes

With these considerations, the current modification to the GYNECARE PROLIFT System was undertaken. The proposed change to the system, from the GYNECARE PROLIFT System to the GYNECARE PROLIFT+M, as described previously, involves modifying only the mesh components of the system and the packaging of that component. The indications for use and the training are essentially unchanged. The new mesh, GYNECARE GYNEMESH M, is a pre-shaped partially absorbable mesh based on ULTRAPRO Partially Absorbable Mesh developed by ETHICON, INC.

ULTRAPRO Mesh is currently indicated for tissue reinforcement and long lasting stabilization of fascial structures of the abdominal wall and used for hernia repair by general surgeons. The mesh includes monofilament polypropylene and fibers of polyglecaprone, the same material used in ETHICON MONOCRYL Monofilament Absorbable Suture. Animal testing of both the

polypropylene substrate and the final mesh adding the polyglecaprone fibers in a rat model showed that the inclusion of the absorbable filaments introduced no short-term complications and no negative impact on biocompatability.[34] Using a rodent model, the authors evaluated both materials after 28, 56, and 84 days of implantation. They reported a slight inflammatory tissue reaction near the mesh filaments involving macrophages and foreign body giant cells. Initial degradation of the absorbable component (in the composite mesh) was noted at 56 days, and all material was absorbed by the 84-day observation period. Although this absorbable material had not previously been used in the construction of a surgical mesh, it has a long history of implantation as MONOCRYL Suture. The authors observed no negative effects on the biocompatibility of PROLENE Mesh with the addition of the absorbable filaments and felt the composite mesh suitable for hernia repair.

The experience reported with mesh implants of varying unit weight (density), pore size, and burst strength indicates that the use of GYNECARE GYNEMESH M, based on ULTRAPRO Mesh, will provide the necessary strength to reinforce tissue and provide long lasting stabilization of the fascial structures in vaginal wall prolapse. GYNECARE GYNEMESH M has burst strength that exceeds two other mesh implants, MERSILENE Mesh and VYPRO Mesh that both have been successfully used for pelvic organ prolapse reported in the literature. GYNEMESH M is biocompatible and elicits minimal foreign body reaction as shown in internally conducted animal studies.

Although several benefits are anticipated with the use of a lower mass mesh implant, the benefits are expected to be subtle and likely difficult to demonstrate in a clinical setting as can be the case with evolutionary improvements. These differences include the potential for a reduction in the rates of mesh exposure and mesh contraction. Of the two, mesh exposure is more common but it is usually considered as a benign complication that can be addressed medically or in some caseswith excision and closure. Mesh retraction ("shrinkage") is a less common complication but considered more significant. Retraction may be associated with vaginal anatomic distortion and the possibility of negatively affecting sexual life or increasing the risk of postoperative pain. Treatment of mesh contraction is difficult, and may require significant effort in attempting to surgically release the vaginal distortion.

Literature Review Conclusion Statement on System Modifications

The above data, taken together with any available pre-clinical data, are sufficient to demonstrate compliance with the essential requirements covering safety and performance of the GYNECARE PROLIFT+M System under normal conditions of use. No additional clinical data is required

Complaint/Adverse Events Review

ETHICON Worldwide Customer Quality was consulted with a request for global product complaints for the GYNECARE PROLIFT Pelvic Floor Repair System. A listing of all global complaints on the products from the original release through January 2007 was provided.

GYNECARE PROLIFT Pelvic Floor Repair System (Product Codes PFRA01, P01 and T01)

From 2005 through early 2007, 113 complaints were reported for the PROLIFT System. Of these, 62 were classified as serious and there was one death reported. The rate of serious complaints was 25 in 2005, 29 in 2006,and 3 in 2007 (including the reported death), with 16 complaints lacking an event date. Mesh exposure was the most commonly reported serious event with 21 reports. Operative injuries were reported in 14 cases with 4 hemorrhages also reported. The patient death was from uncontrolled bleeding. Additionally there were 5 cases of urinary retention and 6 cases of significant pain reported. The number of units sold during this period exceeds 43,000.

The FDA MAUDE database was queried for the term "PROLIFT" for the period 2005 to present. The search returned 54 records, all were submitted by the manufacturer; therefore, all entries would be included in the product complaint review. There have been no recalls or other field corrective actions for this product associated with the product design or materials.

ULTRAPRO MESH Complaint Review

From product release in 2004 through mid-2007, 30 product complaints were recorded for ULTRAPRO Mesh, the material that replaces GYNECARE GYNEMESH PS in the GYNECARE PROLIFT +M Pelvic Floor Repair System. The complaints can be classified as follows:

Type of complaint	Number reported	Comment
Label	3	Not applicable to the current product, as it will be labeled as part of the manufacturing process
Packaging	6	Not applicable to current product, packaging unique to this product will be used
Mesh Tear	9	
Suture/Tack pull through	3	No fixation sutures are used in the current product, only tacking sutures
Infection	4	
Seroma formation	3	
Pain	1	
Material reaction	1	
Total	30	

Further, the 510(k) number and the product brand name were searched in the Manufacturer and User Facility Device Experience Database (MAUDE) database. Seventeen entries were identified from the two keyword searches. They are classified below:

Type of problem	Number reported	Comment
Mesh Tear, rip or hole	7	
Suture/Tack pull through	2	No fixation sutures are used in the current product, only tacking sutures
Hernia recurrence	2	
Infection	4	
Pain	1	
Material reaction	1	
Total	17	

No unexpected problems were identified with the reviews, a low number of problems have been reported with ULTRAPRO Mesh since product launch, and none that are not currently considered in the development of the GYNECARE PROLIFT +M Pelvic Floor Repair System,.

RISK / BENEFIT ANALYSIS:

The primary location for the risk/benefit solution is found in the Risk Management Report. GYNECARE PROLIFT +M Pelvic Floor Repair System is a modification to a currently available system and is intended to be an additional rather than a replacement product. The modification is focused on a change in the mesh material, from non-absorbable PROLENE Mesh to a partially

absorbable mesh that includes a reduced mass of PROLENE Mesh in the construct, adding polyglecaprone fibers (GYENCARE GYNEMESH M). The newer material has been used successfully for a number of years in hernia repair products (as ULTRAPRO Mesh). The newer mesh, as is the mesh currently used in the GYNECARE PROLIFT System, is classified as Type I, monofilament macroporous mesh. Both components, the absorbable and non-absorbable, are well tolerated by the body and the composite mesh has been shown, in bench and modeling studies, to provide adequate strength for pelvic organ prolapse support. The conclusion is the change represents a low risk.

Benefit from the use of a partially absorbable, low mass mesh is mostly theoretical. While reduction in the mass of implant material is desirable; the benefit from this reduction most likely cannot be definitively demonstrated. It is assumed that a reduction in the mass of implanted material will lead to improvements; these may include reduced tissue stiffening and contracture and a resultant reduced awareness of the mesh implant by both the patient and the examining physician. These improvements in turn may reduce patient discomfort, especially during intercourse. The reduced tissue response to the mesh may also lower the rate of mesh exposure events. It is felt, though, that these changes will be subtle and therefore not demonstrable in a clinical study. However, because the risks associated with this modification are low, the risk/benefit ratio is acceptable.

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